REMARKS/ARGUMENTS

The claims are 1-19 and 21-27. Claims 1, 4, 7-13, 18 and 21-23 have been amended to better define the invention. In addition, claim 20 has been canceled in favor of new claims 24-26, claim 7 has been amended to depend on claim 4, claims 21 and 23 have been amended to depend on new claim 24, and new claim 27 has been added containing subject matter previously recited in claim 18. Support for the claims may be found, *inter alia*, in the original claims and page 16 of the disclosure. Reconsideration is expressly requested.

Claims 7-11 and 13 were objected to on formal grounds set forth on page 2 of the Office Action. Claims 11, 20, 18 and 22 were objected to on formal grounds set forth on page 3 of the Office Action. Claims 20-23 were rejected under 35 U.S.C. 101 as being "use" claims. Claims 20-23 were also rejected under 35 U.S.C. 112, second paragraph, for the same reason, and claims 7 and 23 were rejected under 35 U.S.C. 112, second paragraph, as lacking antecedent basis for certain limitations as set forth on page 6 of the Office Action.

In response, Applicants have, *inter alia*, canceled "use" claim 20 in favor of new independent claims 24-26, and have amended claims 7-11, 13, 17 and 21-23 and added new claim 27 to address these informalities. It is respectfully submitted that these amendments overcome the objections to the claims on formal grounds, and Applicants respectfully request that the objection on that basis be withdrawn.

The specification was objected to as lacking antecedent basis for 1,6-octane diol as claimed in claim 8, as the specification refers instead to 1,2-octane diol. In response, Applicants have amended claim 8, *inter alia*, to recite "octane diol," thereby obviating the Examiner's objection.

Claims 4, 7 and 9 were rejected under 35 U.S.C. §112, first paragraph, as encompassing derivatives which in the Examiner's view correspond only in some undefined way to the specifically disclosed chemicals such as lecithin, phosphatidyl choline, and polysaccharide. In response, Applicants have amended claims 4, 7 and 9 to delete reference to such derivatives, thereby obviating the Examiner's rejection on this basis.

Claims 1-7, 9, 11-14, 19-21 and 23 were rejected under 35 U.S.C. 103(a) as being unpatentable over *Owen et al. et al. U.S. Patent No. 5,646,109*. Claim 21 (presumably claim 22) was rejected under 35 U.S.C. 103(a) as being unpatentable over *Pezzuto et al. U.S. Patent No. 6,414,037*. The remaining claims were rejected under 35 U.S.C. 103(a) as being unpatentable over *Owen et al. et al.* in view of *Chen et al. U.S. Patent No. 6,267,985* (claim 8), *Nagahama et al. U.S. Patent No. 6,303,662* (claims 10 and 16), *Nagahama U.S. Patent No. 6,140,375* (claim 15), or *Gehlsen U.S. Patent Application Publication No. 2001/0018059*, *Mooney et al. U.S. Patent No. 5,814,031*, and *Martin U.S. Patent No. 5,674,912* (claim 17).

Essentially, the Examiner's position was that *Owen et al. et al.* discloses the water in oil micro-emulsion, preparation, method and use recited in claims 1-21 and 23, except for features which were considered within the skill of the art or taught by the secondary references to *Chen et al., Nagahama et al. '662, Nagahama et al. '375, Gehlsen, Mooney et al., and Martin*. *Pezzuto et al.* was cited presumably against claim 22 as disclosing a method for preventing or treating skin conditions

such as those that may be associated with natural aging, with the particular ratio of surfactant to co-surfactant, using alcohol in the micro-emulsion, and the particular amount of water to be included being considered within the skill of the art.

This rejection is respectfully traversed.

As set forth in claim 1 as amended, Applicants' invention provides water-in-oil micro-emulsion, with binary phase differentiability and active substance differentiability, wherein it is free of cross-linking agents and includes

a) 45 to 90 wt.-% of a liquid oil phase;

b) 5 to 40 wt.-% of a mixture of one or more W/O and one or more O/W surfactants, in a ratio of 1:4 to 1:1.2;

c) 0.01 to 20 wt.-% of one or more emulsifiers;

d) 0.00 to 15 wt.-% of one or more monovalent C1-8 alcohols, hexane diol, or octane diol;

e) 1 to 10 wt.-% water or aqueous solutions,

wherein the micelles of this primary micro-emulsion have a particle size of 20 to 400 nm, and the emulsion is convertible to

a secondary W/O or an O/W micro-emulsion by means of reactors with an aqueous phase.

Claims 18 as amended and new claim 27 are respectively directed to a topically applicable preparation comprising a mixture of this primary micro-emulsion with an aqueous phase (claim 28) and this micro-emulsion (claim 27), claim 19 is directed to a method for the production of a micro-emulsion as recited in claim 1 as amended, and new claims 24-26 are directed to a method for topically treating skin, a cosmetic, dermatological, pharmaceutical preparation, and a method for treating and caring of hair using this micro-emulsion.

In this way, Applicants' invention provides a skin compatible micro-emulsion that is suitable for the treatment of hair and skin based on a primary W/O micro-emulsion that is convertable into both a secondary W/O and into a secondary O/W micro-emulsion and can contain both water soluble and fat soluble active substances in stable form, which can be produced easily without greater technical effort and can be used both in cosmetics and in medicine (dermatology).

Although the Examiner has taken the position that the feature as previously worded in claim 1 (that the emulsion can be "optionally" converted to a secondary W/O micro-emulsion or an O/W micro-emulsion) can be interpreted two different ways, namely just as a W/O micro-emulsion or a W/O or O/W micro-emulsion after adding an aqueous phase, it is respectfully submitted that this position is not correct. It is respectfully submitted that claim 1 clearly reflects the convertability of the micro-emulsion as a characteristic feature irrespective of whether the micro-emulsion is converted. Claim 1 describes the characteristic feature - - the actual convertability into a secondary W/O micro-emulsion or an O/W micro-emulsion by adding water, whereby the physical state of the micro-emulsion is maintained. This micro-particulation is not mandatorily achieved as can be seen from *Owen et al* discussed below because normally the addition of water to micro-emulsions changes the physical state to normal macro-emulsion. Accordingly, it is respectfully submitted that the claimed micro-emulsion can be interpreted in fact only one way, namely as a micro-emulsion, whether an aqueous phase is further added or not. Nevertheless, Applicants have amended claim 1 to delete "optionally" for clarification purposes.

Owen et al. is concerned with a W/O micro-emulsion which readily converts into an O/W-emulsion by addition of aqueous fluid, See Abstract, Summary of the Invention, col. 2, lines 64 and following and claim 1 of *Owen et al.* Thus, the *Owen et al.* micro-emulsion is not directly converted into a following micro-emulsion, but rather into a normal macro-emulsion. Therefore, it is respectfully submitted that the Examiner's assertion that *Owen et al.* discloses a W/O micro-emulsion which is formulated so that it can be converted into an O/W micro-emulsion is incorrect.

The respective citation at col. 3, lines 56 - 59 in *Owen et al.* is related to a "particular embodiment" of *Owen et al.*. See col. 3, line 56 of *Owen et al.*. Such particular embodiment is further described in detail in col. 12, lines 25 and following of Owen et al where it can be found: "It has been surprisingly found that by taking a certain W/O emulsion system of the present invention and adjusting it to have a higher effective HLB value, that the W/O micro-emulsion converts upon addition of water, not just to an O/W micro-emulsion as to all of the claimed W/O micro-emulsion, but rather to an O/W micro-emulsion." Such change in the HLB

value is achieved by adding specific modifiers. See col. 12, lines 33-43 of *Owen et al.*. Such modifiers are sorbitol, mannitol, other saccharides and polyethylene glycol (PEG), or propylene glycol. Thus, without adding these modifiers the *Owen et al.* W/O emulsion will not be convertible into an O/W micro-emulsion; however, with Applicants' water-in-oil micro-emulsion as recited in claim 1 as amended, modifiers are not necessary, and if any further additives are chosen, then such additives are only those alcohols as recited in claim 1 as amended.

Moreover, it is doubtful that the alcohol compounds mentioned by *Owen et al.* can actually be able to augment the HLB. There is only one example (example 16) in *Owen et al.* directed to W/O to O/W micro-emulsion convertability wherein no propylene glycol is used. This example uses sorbitol (which is a chemically reduced sugar): "The W/O micro-emulsions were formulated with a sorbitol [30 %] in saline solution which allowed for the formulation of the W/O micro-emulsion at higher HLB values than those required for W/O micro-emulsions without the presence of the sorbitol solution.

The higher HLB value allows the system to convert into an O/W micro-emulsion".

Example 16 is the only example in *Owen et al.* wherein in fact such an O/W micro-emulsion is disclosed showing the specific modifiers required. Such difference may also be seen from the composition of the micro-emulsion of *Owen et al.* According to claim 1 of *Owen et al.*, it is specifically designed to administer water soluble active ingredients, whereas in Applicants' claim 1 as amended both water as well as oil soluble active ingredients may be used to be administered with the presently claimed micro-emulsion comprising only up to 10 % water or aqueous phase.

Thus, only the particular embodiment of *Owen et al.* may be cited to reflect a W/O micro-emulsion being convertible into an O/W micro-emulsion whereas in the composition claimed by *Owen et al.* as such a convertability is not possible. Consequently, it is respectfully submitted that the subject matter of *Owen et al.* can be interpreted two different ways -- namely the O/W micro-emulsion on the one hand and the specific embodiment thereof comprising specific modifiers on

the other hand, both leading to different subsequent products upon addition of water, contrary to Applicants' water-in-oil micro-emulsion as recited in claim 1 as amended, which it is respectfully submitted represents a clear difference over *Owen et al.*.

Furthermore, Applicants' water-in-oil micro-emulsion as recited in claim 1, as amended, includes 1 - 10 % of water or watery solutions. According to *Owen et al.*, as the Examiner did point out, the emulsion includes up to 20 vol %, preferably 30 - 60 % water. See col. 5, lines 20 -23 of *Owen et al.*. This volume percent of *Owen et al.* represents another clear difference. In addition, the one preferred W/O micro-emulsion of *Owen et al.* as cited by the Examiner at page 12 of the Office Action as mentioned in col. 2, lines 53 - 54 and col. 14, line 49 of *Owen et al.* does not describe an emulsion containing the modifiers mentioned by *Owen et al.* as necessary for producing O/W micro-emulsion from W/O micro-emulsions and is therefore not convertible. Such emulsions are designed for the administration of water soluble active ingredients.

Applicants' micro-emulsions as recited in claim 1 as amended, however, can be used for the administration of both water soluble and oil soluble active ingredients (see Applicants' claim 2) and moreover can be converted into further micro-emulsions without the addition of specific stabilizers. From the disclosure in the *Owen et al.*, which does not also use different surfactants, it is respectfully submitted that it would have been completely unobvious to choose a specific combination of surfactants and emulsifiers to prepare an emulsion which is stable and convertible into secondary micro-emulsions with the maintenance of the micro particle size and moreover which exhibits an active ingredient differentiability.

Although the Examiner has taken the position that it would have been obvious in view of *Owen et al.* to vary the amounts of alcohol depending on the other water soluble agents added, it is respectfully submitted that *Owen et al.* does not at all suggest any alcohols at col. 5, line 43 - 46 as solution agents as cited by the Examiner, but rather suggests specific modifiers such as mono- and disaccharides, sorbitol and mannitol (which are hexavalent polyols), PEG, or even

propylene glycol as mentioned above as a means to prepare O/W micro-emulsions starting from the W/O micro-emulsions.

Thus, it is respectfully submitted that Applicants' claim 1 as amended cannot represent an obvious step starting from *Owen et al.*, because *Owen et al.* if at all suggesting alcohols, fails to disclose or suggest univalent alcohols and mainly suggests other components to prepare such micro emulsions. Moreover, in Applicants' claim 1 as amended, alcohol can also be absent. Such subject matter will not be possible following the teachings of *Owen et al.*.

Consequently, it is respectfully submitted that Applicants water-in-oil emulsion as recited in claim 1, as amended, cannot be considered obvious over *Owen et al.* for the additional reasons with regard to the ratio of the surfactants because the claimed phase differentiability (allowing conversion without modifiers) could not be derived from *Owen et al.* wherein the phase differentiabilitiy is depending on specific modifiers in contrast to Applicants' claim 1 as amended.

As explained above, *Owen et al.'s* process is entirely dissimilar to Applicants' method in view of the lack of adding modifiers to produce the converted micro-emulsions.

As to the Examiner's objection concerning the incorporating of fat soluble ingredients in *Owen et al.* emulsions at col. 5, line 62 - 63, it should be noted that according to the complete wording of *Owen et al.*, only in case of a high water content can ingredients with a low solubility or high amounts of active ingredients be chosen. It is respectfully submitted that 10 % water as recited in Applicants' claim 1 as amended is not a high water content and that consequently the *Owen et al.* emulsion is not appropriate to actually include oil soluble active ingredients.

The defects and deficiencies of the primary reference to *Owen et al.* are nowhere remedied by the secondary references to *Chen et al., Nagahama et al.'662, Nagahama et al. '375, Gehlsen, Mooney et al. and Martin.*

Chen et al. is concerned with pharmaceutical compostions and an improved solubilibilty of triglycerides. See abstract

of *Chen et al.* Alcohols can be added to specifically enhance the solubility of the therapeutic agent or the triglyceride. See col. 33, line 65 - 67. Amongst such solubilizers there can be ethers of PEG, esters, amides or alcohols. As mentioned above, *Owen et al.* does not mention at col. 5 (as cited by the Examiner, see above) such solubilizers. The compounds of *Owen et al.* are chosen in view of a possible convertability. In Applicants' micro-emulsion as recited in claim 1 as amended, the alcohols are neither used for enhancing solubility of any compounds nor for providing convertability. Consequently, it is respectfully submitted that it would not possible to arrive at Applicants' micro-emulsion as recited in amended claim 1 when combining *Owen et al.* and *Chen et al.*, the more so as *Chen et al.* does not disclose micro-emulsions, but rather clear aqeuous dispersions composed of triglyceride and surfactants. See claim 1 of *Chen et al.*

With respect to *Nagahama et al. '662,* Applicants do not contest that certain specific active ingredients are known in the art; however, *Owen et al.* nowhere discloses the use of oil soluble agents, but rather only agents which are less water soluble, with the consequence that a high water content is

necessary. Such teaching clearly shows that such agents cannot be oil soluble, because otherwise the higher water content would lead to the deposition of that agent. Consequently, even though *Nagahama et al. '662* discloses fat soluble agents, it is respectfully submitted that a combination of *Nagahama et al. '662 with Owen et al.* cannot lead to the microemulsion set forth in Applicants' claim 1 as amended because *Owen et al* does not disclose the possible inclusion of fat soluble agents in stable micro-emulsions of the present kind.

The Examiner has cited *Nagahama et al. '375* as regards flavors especially sugar. Such additive, namely indicated as sweetening agent, is used when the *Nagahama '375* composition is applied in the field of foods. See col. 8, line 15 of *Nagahama '375*. In Applicants' water-in-oil emulsion, the saccharide can be incorporated as active ingredient, because in topical applications it can serve as a humectant for skin. See also example 9, table 4 and page 35, point 2c of Applicants' disclosure. Thereby the sugar active ingredient is used in very low amounts (1 %), whereas if *Owen et al.* uses sugar, the amounts thereof are high. See example 16 (30 %),

as discussed see above.

With respect to *Gehlsen, Mooney et al. and Martin*, as discussed above, Applicants do not contest that certain active ingredients as such are known; however, it is respectfully submitted that it could not have been obvious to one of ordinary skill in the art to choose such agents in view of stability and solubility problems which may arise in micro-emulsions as it is clearly pointed out by *Owen et al.* suggesting high water content and/or modifiers to achieve stable emulsions, see col. 5, line 57 - 61, which presently is not performed, as discussed above.

Pezzuto et al.et al. has been considered but is believed to be no more relevant. Although *Pezzuto et al.et al.* discloses a method for preventing or treating skin conditions, there is no disclosure or suggestion of using the micro-emulsion as recited in Applicants' claims for such treatment.

More specifically, *Pezzuto et al.* is clearly related to a method of preventing or treating skin conditions using as the pharmaceutically active ingredient resveratrol which is a

3,5,4'-trihydroxystilbene. See col. 1, under "Technical Field" and col. 4, lines 35-50. Thus, the main ingredient in the *Pezzuto et al.* reference is such compound. The aim according to *Pezzuto et al.* is the topical administration of the said compound because until *Pezzuto et al.* resveratrol has only been used orally, preferably as the trans-isomer. See col. 3, 1st para and col. 3, lines 31-40. Thereby only certain specific skin conditions can be treated. See col. 3, lines 34-35.

Because the active compound is administered topically, different formulations in the form of a useful carrier are possible for that purpose such as an ointment, a gel, a lotion, a cream, an oil or a micro-emulsion. See col. 7, lines 50-55 whereby such forms are further specified by individual carriers such as mineral oil, water, lanolin, petrolatum. See col. 7, lines 56-63.

In regard to micro-emulsions (col. 8, line 53 to col. 9, line 11), there is no indication as to the specific tensids as recited in Applicants' claims, and where additives such as polyethylene glycol are present, these are added to the water

phase. See col. 9, line 3-6. Consequently, and as the Examiner did correctly observe (see page 21 of the Office Action under "Ascertainment of the difference..."- *Pezzuto et al.* does not suggest the use of alcohol as presently claimed or a particular amount of water in the micro-emulsion. Consequently, it is respectfully submitted that the Examiner's assertion that one would have been motivated to use alcohol (page 21, 2nd to last line up to page 22, 1st para) cannot be correct because not only is there no disclosure or suggestion of alcohol, but also there is no disclosure or suggestion to help facilitate the passage of therapeutic levels of active agents as the Examiner did point out.

Furthermore, as previously pointed out, alcohol is not mandatory in Applicants' claim 1 as amended, and moreover, if it is used, then it is not - and therefore contrary to *Pezzuto et al.* - added to the water phase, but rather to the oil phase. See Applicants' disclosure at page 41, 1st para, especially lines 1-3.

Furthermore in amended claim 21, against which *Pezzuto et al.* has been cited, the active ingredient that *Pezzuto et al.*

requires is not necessary as can be taken from present examples. Applicants' invention relates to a specifically designed micro-emulsion with a binary phase differentiability and active substance differentiability (see page 1, 1st para of the Applicants' disclosure) showing a significant penetration into the deeper skin layers, see example 20 whereas the *Pezzuto et al.* micro-emulsion corresponds solely to those already cited in Applicants' disclosure as state of the art and the aim of *Pezzuto et al.* is the topical administration of a specific stilbene-compound. To summarize, it is respectfully submitted that *Pezzuto et al.* cannot give any motivation to the claimed subject matter, because all decisive features mentioned by *Pezzuto et al.* are not decisive or not even made whereas other features have been chosen or never even suggested by the art.

Accordingly, it is respectfully submitted that all currently pending claims recite patentable and unobvious subject matter.

In summary, claims 1, 4, 7-13, 18, and 21-23 have been

amended, claim 20 has been canceled, and new claims 24-27 have been added. A check in the amount of $285.00 is enclosed in payment of the fee for three additional total claims over 20 and two additional independent claims over 3 not previously paid for. In view of the foregoing, it is respectfully requested that the claims be allowed and that this case be passed to issue.

Respectfully submitted,

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Copy of Petition for two month extension of time

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